UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SECURITIES AND EXCHANGE COMMISSION,	:	
Plaintiff,	:	Civil Action No. 05-11805-NMG
v.	:	
RICHARD F. SELDEN,	:	
Defendant.	:	
RICHARD F. SELDEN,	:	
Plaintiff,	:	Civil Action No. 06-11807-NMG
v.	:	
UNITED STATES FOOD AND DRUG ADMINISTRATION and ANDREW C. VON ESCHENBACH, in his official capacity as acting commissioner of the United States Food and Drug Administration,	:	
Defendants.	:	

RICHARD F. SELDEN'S MEMORANDUM OF LAW IN SUPPORT OF HIS CROSS-MOTION TO PRECLUDE ADMISSION OF FDA EVIDENCE

Thomas J. Dougherty
Justin J. Daniels
SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP
One Beacon Street
Boston, Massachusetts 02108
(617) 573-4800

Dated: October 27, 2006

Counsel for Richard F. Selden

TABLE OF CONTENTS

PAGE

TABLE OF AUTHORITIES ii

PRELIMINARY STATEMENT 1

BACKGROUND 1

ARGUMENT 5

I. THIS COURT HAS THE INHERENT POWER TO PRECLUDE ADMISSION OF EVIDENCE IN ORDER TO SAFEGUARD THE INTEGRITY AND FAIRNESS OF THIS PROCEEDING 5

II. THE PRECLUSION OF FDA EVIDENCE IS WARRANTED UNDER THE FACTS OF THIS CASE 7

A. The SEC Should Not Be Permitted To Introduce Evidence From The FDA Where Dr. Selden Has Been Prevented From Obtaining Discovery 7

B. Because The Plaintiff In This Case Is The Federal Government, The Need For Preclusion Is All The More Imperative 8

CONCLUSION 9

TABLE OF AUTHORITIES

CASES **PAGE(S)**

Chambers v. NASCO, Inc.,
501 U.S. 32 (1991) 5

Davis v. Lehane,
89 F. Supp. 2d 142 (D. Mass. 2000) 8

In re Atl. Pipe Corp.,
304 F.3d 135 (1st Cir. 2002) 5

Link v. Wabash R.R. Co.,
370 U.S. 626 (1962) 5

Lomascolo v. Otto Oldsmobile-Cadillac, Inc.,
253 F. Supp. 2d 354 (N.D.N.Y. 2003) 6, 7

S.E.C. v. Rivlin,
Civ. No. 99-1455, 1999 WL 1455758 (D.D.C. Dec. 20, 1999) 8

Thibeault v. Square D Co.,
960 F.2d 239 (1st Cir. 1992) 5, 6

Third Wave Tech., Inc. v. Stratagene Corp.,
405 F. Supp. 2d 991 (W.D. Wis. 2005) 6, 7

Ware Commc'ns, Inc. v. Rodale Press, Inc.,
Civ. No. 95-5870, 2002 WL 89604 (E.D. Pa. Jan. 23, 2002) 6, 7

Weinberger v. Great N. Nekoosa Corp.,
925 F.2d 518 (1st Cir. 1991) 5

Westinghouse Elec. Corp. v. City of Burlington,
351 F.2d 762 (D.C. Cir. 1965) 8

OTHER AUTHORITIES **PAGE(S)**

Fed. R. Civ. P. 16(f) 5

Fed. R. Civ. P. 26 ..... 6, 8

Fed. R. Civ. P. 37(b)(2)(B) 5

Fed. R. Civ. P. 45 3

PRELIMINARY STATEMENT

This preclusion motion is based on two simple principles, both of which compel the result: (1) a civil litigant cannot introduce evidence where its opponent has been precluded from adducing documents and testimony likely to lead to admissible evidence on the same subject matter and (2) the government cannot support an enforcement action against a private citizen using evidence from witnesses who are not fully available to that citizen for purposes of discovery.

BACKGROUND

The Securities and Exchange Commission ("SEC") instituted this enforcement action on September 1, 2005, alleging that Richard F. Selden ("Dr. Selden") (the founder and former President and Chief Executive Officer of the small biotechnology firm Transkaryotic Therapies, Inc. ("TKT")), violated federal securities laws in connection with the United States Food and Drug Administration's[1] review of TKT's drug, Replagal, for the treatment of Fabry disease, a rare genetic disorder. According to the SEC's Complaint, Dr. Selden should be held liable under federal securities laws, and barred for the rest of his life from serving as a director and officer of a public company, because of a "series of [allegedly] materially misleading public statements by TKT about the status of the FDA application for Replagal." Complaint ¶ 1. As the Complaint makes clear, the SEC's entire case is based on the FDA's review of TKT's application for Replagal, its communications with TKT in this regard, and the steps both the FDA and TKT perceived as

[1] For purposes of this submission, "FDA" shall refer collectively to defendants the United States Food and Drug Administration and Andrew C. von Eschenbach, in his official capacity as acting commissioner of the FDA.

necessary for Replagal to obtain marketing approval in the United States. See, e.g., id. ¶¶ 2-4, 12-14, 21-22, 24-26, 28-33, 35, 38-39, 41-42, 44-53, 55, 59-60, 62, 66, 70 & 74.[2]

However, the SEC's case against Dr. Selden did not begin on September 1, 2005. It began three years earlier, in October of 2002, when the SEC commenced its investigation and started collecting information, documents and testimony on the same issues now presented in the SEC's enforcement action. During this ex parte process, the SEC had total discretion and no time limits; it could ask for what it wanted, when it wanted it, and had as part of its arsenal the government's full subpoena power.

For example, both TKT and Dr. Selden received subpoenas during the SEC's investigation. In Dr. Selden's case, the SEC's subpoena demanded all responsive documents within twenty days of the subpoena; and, as required, Dr. Selden produced within twenty days of the subpoena all 7,723 pages of responsive documents in his possession, custody or control. TKT also produced tens of thousands of pages of documents and also agreed to waive the attorney-client privilege, allowing the SEC to expand the reach of its inquiry even further.

In addition, the SEC sought and obtained extensive information from the FDA, including the voluntary production of documents and testimony. The FDA also provided substantive assistance to the SEC, including assistance from some of the same

---

[2] The SEC contends that its case is not only about the FDA's review of TKT's application for Replagal, but is also about representations concerning the "clinical test results for Replagal." See SEC's "Statement Of Position Concerning Motion For Preliminary Injunction," Selden v. FDA, et al., Civ. No. 06-11807-NMG (D. Mass.), at 2 n.1. That distinction is without a difference because the relevance attributed in the SEC's Complaint to the clinical test results is how they impacted the FDA application. See, e.g., Complaint ¶ 2. Either way, the FDA is central to the SEC's case.

individuals responsible for the FDA's review of TKT's Replagal application.[3] For example, within weeks after the start of the investigation, the FDA began allowing SEC staff members to conduct informal, "off the record" interviews of key FDA witnesses.[4] Only after the SEC was satisfied that it had everything it needed did the SEC finally bring its suit against Dr. Selden.

Dr. Selden had no such luxury. In order to secure the discovery needed for his defense, Dr. Selden followed the processes in the Federal Rules of Civil Procedure, including serving Rule 45 subpoenas on the FDA. He has now pursued that discovery for a year; and he has been as energetic as possible in this endeavor.

In contrast to the cooperation and openness provided to the SEC, the FDA's response to Dr. Selden has been one of non-cooperation and stonewalling. In fact, since the time Dr. Selden first issued his subpoenas in late October 2005, the government has done essentially everything in its power to oppose Dr. Selden's effort to obtain discovery. Among the positions taken by the FDA are the following:

- claiming it was not a "person" under the Federal Rules and therefore could not be subpoenaed;
- stating that even if it was a person, it did not have to comply with the subpoena because its internal regulations overrode the Federal Rules;
- providing a series of boilerplate reasons why documents could not be made available;

---

[3] Also, in early February 2004, in the midst of the investigation, the SEC and FDA simultaneously announced their partnership relating to securities law enforcement. The relevant announcements and press releases can be found on the FDA's website at http://www.fda.gov/bbs/topics/NEWS/2004/NEW01019.html.

[4] Further detail on the FDA's assistance to the SEC, and other related background, is set forth in Dr. Selden's Proposed Findings Of Fact And Conclusions Of Law, submitted as part of this motion.

- at first telling Dr. Selden that his subpoenas could not be construed alternatively as FOIA requests, and then, after a federal court ruled months later that the subpoenas were in fact proper FOIA requests, claiming that Dr. Selden should have followed the FOIA procedures to begin with;

- now arguing that this Court does not even have subject matter jurisdiction over this dispute; and

- now arguing that only the D.C. Court can or should adjudicate the FDA discovery timing.

To further prejudice Dr. Selden, the FDA did nothing to work on his requests while these issues were in dispute. Instead, the FDA let ten months pass with no action at all, and only within the last several weeks has it started to provide any documents. It now says it will take an additional 22 months to complete production.

The SEC has joined its sister agency in trying to limit Dr. Selden's access to FDA evidence. See SEC's "Statement Of Position Concerning Motion For Preliminary Injunction," Selden v. FDA, et al., Civ. No. 06-11807-NMG (D. Mass.), Docket No. 9. In that submission, the SEC asks this Court to accept the FDA's 22-month timetable and instead force Dr. Selden to further cut back his requests. In other words, the SEC's position is that Dr. Selden should be the one to deal with the consequences of the FDA's unreasonable delay.[5]

Dr. Selden is subject to charges of fraud by the very agencies that have not provided him with the documents he needs for development of his case and cross examination of witnesses. The government would preclude Dr. Selden access to key

[5] In its own investigations, the SEC takes into account the degree of respondents' cooperation. See, e.g., "Memo from Larry D. Thompson, Deputy Attorney General, to Heads of Department Components, United States Attorneys regarding the Principles of Federal Prosecution of Business Organizations" (Jan. 20, 2003) (the "Thompson Memo") (available at http://www.usdoj.gov/dag/cftf/corporate_guidelines.htm) (respondent cooperation is a factor in enforcement decisions).

witnesses -- that have additional relevant information. It is well within this Court's inherent power to preclude the SEC from introducing FDA evidence on dispositive motions or at trial of this matter under these circumstances.

ARGUMENT

I. THIS COURT HAS THE INHERENT POWER TO PRECLUDE ADMISSION OF EVIDENCE IN ORDER TO SAFEGUARD THE INTEGRITY AND FAIRNESS OF THIS PROCEEDING

It is a basic principle of our federal judicial system that courts have the inherent power to manage and control the disposition of the cases on their dockets to promote "the enhancement of the court[s'] processes," In re Atl. Pipe Corp., 304 F.3d 135, 143 (1st Cir. 2002), and to ensure the courts' fundamental role as "a guarantor of fairness," Weinberger v. Great N. Nekoosa Corp., 925 F.2d 518, 525 (1st Cir. 1991). As held by the United States Supreme Court: "These powers are 'governed not by rule or statute but by the control necessarily vested in courts to manage their own affairs so as to achieve the orderly and expeditious disposition of cases.'" Chambers v. NASCO, Inc., 501 U.S. 32, 43 (1991) (citing Link v. Wabash R.R. Co., 370 U.S. 626, 630-31 (1962)).[6]

The exercise of the court's power over the matters before it can "take[] many forms." Atl. Pipe, 304 F.3d at 143. As held by the First Circuit Court of Appeals: "This circuit has recommended a straightforward approach to ensure that the spirit of open discovery embodied in Rule 26 is not undermined either by evasion or by dilatory tactics."

---

[6] The Federal Rules of Civil Procedure also provide means for protecting the integrity of federal actions. For example, when a party affirmatively withholds discovery from its opponent without substantial justification, Rule 37 provides sanctions -- such as precluding the party from using such evidence -- unless the failure to disclose is harmless. See, e.g., Fed. R. Civ. P. 37(b)(2)(B) (providing that an appropriate sanction for failing to obey a discovery order is to "prohibit[] that party from introducing designated matters in evidence"). Rule 16(f) also permits a court to impose any sanctions "as are just" (including preclusion sanctions permitted under Rule 37(b)(2)) for failure to obey a scheduling or pre-trial order. See Fed. R. Civ. P. 16(f).

Thibeault v. Square D Co., 960 F.2d 239, 244 (1st Cir. 1992). Among other things, this Court can preclude evidence when there is unfairness or unequal treatment in discovery. Indeed, there are numerous situations where courts have reasonably imposed the sanction of preclusion against a party who fails to comply with discovery obligations or who acts to prevent the timely and fair completion of discovery.

For example, in Third Wave Tech., Inc. v. Stratagene Corp., 405 F. Supp. 2d 991 (W.D. Wis. 2005), defendant challenged various rulings by the district court after an unfavorable jury verdict finding patent infringement; among them, the Court's preclusion of evidence from defendant's general counsel on the grounds that during discovery defendant had prevented plaintiff from exploring the full extent of that witness's communications with another key witness. The Court reaffirmed its decision precluding the evidence, holding that "[i]t is not my practice to let a party introduce evidence at trial on a relevant topic that it has prevented its adversary from exploring during discovery." Id. at 999.

In Lomascolo v. Otto Oldsmobile-Cadillac, Inc., 253 F. Supp. 2d 354 (N.D.N.Y. 2003), during the trial of plaintiff's Title VII claims, the defendant-employer had moved for a protective order to preclude the plaintiff-employee from using documents allegedly required in initial disclosures but first disclosed during depositions. The Court ruled that because plaintiff's initial position was that such documents were not required disclosures, he was precluded from using those documents during the trial for any purpose other than impeachment. Id. at 358-61.

In Ware Commc'ns, Inc. v. Rodale Press, Inc., Civ. No. 95-5870, 2002 WL 89604 (E.D. Pa. Jan. 23, 2002), defendant had sought to preclude plaintiff from introducing damages evidence at trial because plaintiff's counsel did not timely comply with discovery

requests seeking this information and only produced the information on the eve of trial. Though the Court recognized that its ruling effectively dismissed plaintiff's claim because it precluded all evidence going to an element of the prima facie case, the Court nevertheless granted defendant's motion to preclude, finding, inter alia, that plaintiff's actions had prejudiced defendant by "substantially imped[ing] [d]efendant's ability to prepare a full and complete defense." Id. at *3.

In this case, as in Third Wave, Lomascolo and Ware, this Court has the inherent authority to protect the fair disposition of this matter, including ordering the preclusion of evidence.

II. THE PRECLUSION OF FDA EVIDENCE IS WARRANTED UNDER THE FACTS OF THIS CASE

A. The SEC Should Not Be Permitted To Introduce Evidence From The FDA Where Dr. Selden Has Been Prevented From Obtaining Discovery

FDA evidence must be precluded to preserve the fairness of this case. The FDA is a most important witness in this matter and is certainly central to Dr. Selden's defense. Yet despite the unfettered access, cooperation and assistance that the FDA has provided to the SEC, the FDA has tried essentially every means in its power to oppose Dr. Selden's legitimate attempt to seek his own access to information. Further, the SEC itself has now joined in this effort, seeking to limit the types of discovery that Dr. Selden may obtain from the FDA. In other words, Dr. Selden's access to this witness has been substantially compromised in light of the tactics and arguments employed by the FDA, now supported by the SEC. Preclusion is therefore warranted.

B. Because The Plaintiff In This Case Is The Federal Government, The Need For Preclusion Is All The More Imperative

The government's actions fly in the face of the spirit of open discovery embodied in Rule 26 and would never be tolerated by a private litigant. However, in this case, the circumstances are even more problematical.

Here, the plaintiff is the federal government, and the federal government has accused an individual citizen of committing securities fraud. In attempting to restrict Dr. Selden's access to potentially exculpatory information, the government's conduct also threatens Dr. Selden's rights to due process and access to the courts. See S.E.C. v. Rivlin, Civ. No. 99-1455, 1999 WL 1455758, *3 (D.D.C. Dec. 20, 1999) (recognizing that a defendant has "full due process rights" when "the SEC, pursuant to its investigation, either files a complaint or makes a criminal reference") (citation omitted). For example, in Davis v. Lehane, 89 F. Supp. 2d 142, 155-56 (D. Mass. 2000) (Young, C.J.), the Court held that a government official's efforts to convince a relevant witness not to be interviewed by the petitioner constituted a violation of the petitioner's due process rights. As stated by the D.C. Circuit, "the paramount interest of the Government in having justice done between litigants in the Federal courts militates in favor of requiring a great effort on its part to produce any documents relevant to a fair termination of this litigation." Westinghouse Elec. Corp. v. City of Burlington, 351 F.2d 762, 767 (D.C. Cir. 1965). The government's actions in this case are an affront to that goal.

CONCLUSION

For these reasons, Dr. Selden respectfully submits that the Court should enter an Order precluding the SEC from relying on or introducing on dispositive motions or at trial any materials, testimony or other evidence derived or received from the FDA, any of its sub-agencies or departments, or any of its current or former employees.

Dated: October 27, 2006
Boston, Massachusetts

Respectfully submitted,

/s/ Thomas J. Dougherty

Thomas J. Dougherty (BBO #132300)
Justin J. Daniels (BBO #656118)
SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP
One Beacon Street
Boston, Massachusetts 02108
(617) 573-4800
dougherty@skadden.com
jdaniels@skadden.com

Counsel for Richard F. Selden

CERTIFICATE OF SERVICE

I, Justin J. Daniels, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on October 27, 2006.

Dated: October 27, 2006

/s/ Justin J. Daniels
Justin J. Daniels